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COMPLETE SPECIFICATION

# COLOSTRUM PREPARATION AND STORAGE

We, MINISTER OF AGRICULTURE A BODY CORPORATE PURSUANT TO THE MINISTER OF AGRICULTURE INCORPORATION ACT 1952 of 19th Floor, Grenfell Centre, 25 Grenfell Street, Adelaide, South Australia 5000, Australia

do hereby declare the invention for which I/we pray that a Patent may be granted to me/us, and the method by which it is to be performed, to be particularly described in and by the following statement:

This invention relates to a process for the preparation and storage of colostrum products. It is particularly applicable to preparing and storing antibody enriched colostrum without loss of the antibody activity.

Colostrum is the milk secreted by a mammal just before and for a short period after giving birth, containing antibodies to protect offspring against disease. It has been recognised in the prior art that mammals such as cows may be immunized with specific antigens. The antibody enriched colostrum may then be harvested.

A difficulty in the prior art has been that there has been no economical process for preparing and storing colostrum products.

It is known in the prior art that milk products may be spray dried to give a powdered product which may be stored. When known spray drying processes were used to process colostrum it was unexpectedly discovered that the high salt content of the colostrum was a problem which rendered known processes uneconomical.

Colostrum has an extremely high salt content. If known spray drying processes are used to process colostrum the spray drier must undergo extensive cleaning every day for approximately 10 hours to prevent corrosion of the drier. As indicated above this renders the process uneconomic and is a problem which does not relate to normal milk.

Accordingly, it is an object of the present invention to overcome or at least alleviate, one or more of the difficulties related to the prior art.

Accordingly as a first aspect of the present invention there is provided a process for the preparation of a colostrum product which process includes:

providing colostrum;

removing or substantially reducing the salt content of said colostrum; and

subjecting the colostrum to a spray drying process.

The inventors have found that the step of removal

of salt from the colostrum renders the process economic. Salt removal is significant as it reduces the likelihood of corrosion damage to stainless steel plant and reduces the necessity to wet wash drying equipment, offering a significant saving of time and money.

The colostrum may be freshly harvested colostrum or frozen colostrum. The colostrum may be bovine colostrum harvested from freshly calved cows. The colostrum may be harvested using modern milking equipment. The colostrum may be antibody enriched.

The salt may be removed by any suitable means. In a preferred embodiment the salt is removed by ultra-filtration.

Accordingly in a further aspect of the present invention, there is provided a process for the preparation of a colostrum product which process includes

providing colostrum;

subjecting the colostrum to an ultra-filtration process; and

subjecting the filtered colostrum to a spray drying process.

The product so formed is provided in a preserved form without loss of antibody activity.

The ultra-filtration apparatus preferably removes all molecules of molecular weight less than 20,000 for example water, minerals, salts and non-protein nitrogen. Any suitable ultra-filtration apparatus may be used. In a preferred embodiment a hollow fibre ultra-filtration plant is used. The ultra-filtration step may also remove or reduce the lactose from the content of the colostrum. This is also advantageous from a medical point of view.

In a preferred aspect of the present invention the process may further include the preliminary step of pasteurisation. Low temperature, long time pasteurisation is preferably employed due to the extreme heat sensitivity of immuno-proteins. In a preferred embodiment the pasteurisation is conducted at approximately 63°C for approximately 30 minutes. The pasteurised colostrum is then preferably cooled to approximately 55°C before

undergoing the ultra-filtration step. The pasteurised colostrum may suitably be cooled by regeneration.

Accordingly, a further aspect of the present invention provides a process for the preparation of a colostrum product which process includes

providing colostrum;

subjecting the colostrum to a pasteurisation process;

subjecting the pasteurised colostrum to an ultra-filtration process; and

subjecting the filtered colostrum to a spray drying process.

In a further preferred aspect of the present invention the process may further include the preliminary step of separating the colostrum. The colostrum may be preferably separated into a light phase (cream) and a heavy phase (skim). The light phase is preferably discarded.

Accordingly yet a further aspect of the present invention provides a process for the preparation of a colostrum product which process includes

providing colostrum;

subjecting the colostrum to a separation step and discarding the light phase;

subjecting the heavy phase colostrum to a pasteurisation process;

subjecting the pasteurised colostrum to an ultra-filtration process; and

subjecting the filtered colostrum to a spray drying process.

Any suitable separation apparatus may be used. A suitable separation apparatus is a self desludging type apparatus.

The colostrum is preferrably pre-heated to approximately 50°C prior to the separation step. Any suitable means may be used to preheat the colostrum, for example by means of a plate heat exchanger.

After the ultra-filtration step, it is preferred that the ultra-filtered retentate is subjected to an

evaporation step in which excess moisture is removed from the retentate. In a preferred embodiment, the excess moisture is boiled off under a vacuum of approximately -100kpa. At this pressure, the vapour temperature is maintained at approximately 45°C thus minimising any heat damage. Any suitable evaporator may be used. In a preferred embodiment a centritherm evaporator is used.

The concentrate may then be introduced into the spray drying chamber. The concentrate may be introduced at the same temperature at which pasteurisation has occured. In a preferred embodiment it is introduced at a temperature of 63°C. A two-fluid nozzle may be used to introduce the concentrate into the drying chamber. In a preferred embodiment, the drying chamber is maintained at approximately 170°C inlet temperature and 70°C outlet temperature. The Applicants have unexpectedly found that this drying technique which normally would be expected to inactivate the antibodies, has been found by the Applicants not to do so. Most of the energy of the spray drying is taken up as latent heat of evaporation, and accordingly there is very little particle temperature elevation. Accordingly heat damage is minimised. The dried particles preferably fall into a static fluidised bed where further drying and fines agglomeration take place. This produces a product with good dispersibility in water.

It will be understood that the steps of the process of the present invention as described above may take place in any suitable order. Other steps may also be included in the process of the present invention. For example in another preferred embodiment of the present application casein is removed from the milk by precipitation. This step preferably takes place after the colostrum has been subjected to a separation step and the light phase has been discarded.

The present invention will now be more fully described with reference to the accompanying drawings and example. It should be understood, however, that the description following is illustrative only, and should not

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be taken in any way as a restriction on the generality of the invention described above.

In the drawing:

Figure 1 is a flow diagram of the process according to one embodiment of the present invention. The abbreviations used are as follows, SEP=SEPARATION, PAST 1=PASTEURISATION, UFS-10=ULTRAFILTRATION, UFS-1=ULTRAFILTRATION, CT1B=CENTRITHERM (Thermal Evaporator), P3 HEATER=PLATE HEAT EXCHANGER, HT1=HOLDING TUBES, HT2=HOLDING TUBES and HT3=HOLDING TUBES.

EXAMPLE 1

Antibody enriched bovine colostrum was harvested from freshly calved cows using modern milking equipment. The colostrum was quickly cooled and held under refrigeration (<4°C) until it was collected. The colostrum was collected daily in a refrigerated van (0°C). Colostrum from individual farms was segregated to prevent cross-contamination.

The colostrum was weighed and tested for microbial quality, inhibitory substances and for specific antibodies to known pathogens. The colostrum was then stored at 0°C pending the results of these tests.

The liquid colostrum was pooled according to antibody content, to produce a uniform product. The pool was kept refrigerated prior to processing.

The pooled colostrum was pre-heated to 50°C by means of a plate heat exchanger and separated in a self desludging type separator. The light phase (cream) was discarded and the heavy phase (skim) was pasteurised at 63°C for 30 minutes. The pasteurised skim was cooled by regeneration to 55°C.

The skim was passed through a hollow fibre ultra-filtration plant to remove molecules of molecular weight less than 20,000; namely water, lactose, minerals, salts, non-protein nitrogen. The ultra-filtered retentate was transferred to a centritherm evaporator where excess moisture was boiled off under a vacuum of -100kpa. After evaporation, the concentrate underwent a further pasteurisation step at 63°C for 30 minutes to reduce microbial loading prior to spray drying.

The concentrate, at 63°C, was introduced into a spray drying chamber of aseptic design with hepa filters

in the feed line, atomising air, and drying air supply, purpose built for pharmaceutical grade products. The concentrate was introduced via a two-fluid nozzle where it was atomised by heated, hepa-filtered air. The drying chamber was maintained at 220°C inlet temperature and 70°C outlet temperature. The dried particles fell into a static fluidised bed where further drying and fines agglomeration took place, producing a product with good dispersibility in water. The finished product was then packaged.

EXAMPLE 2

Antibody levels and quantities of colostrum collected from cows varies dramatically over the first week after calving. The colostrum from the first six milking was collected. For practical handling reasons all milk collected on one day was pooled at each farm with each farms milk kept separate by collection date. Each of these milk deliveries was kept separate and assessed individually for quality. Colostrum deliveries shown to be satisfactory with respect to microbial and inhibitory substances tests were pooled on the basis of quantity and haemagglutination inhibition (HAI) titre to produce a standard weight average HAI titre. This pooling step ensured that a standard product was consistently produced with respect to both the colostrum composition and antibody potency.

Approved milk pooled for processing to provide correct antibody levels was processed by skimming in a cream separator to reduce fat, low temperature pasteurisation to reduce microbiological load and eliminate major potential pathogens, ultra filtration to concentrate protein and reduce lactose and mineral levels, including salt, evaporation under vacuum to further concentrate, and spray drying in an aseptic, pharmaceutical model spray drier with filtered air supply. Powder was packed in new food grade poly-ethylene bags within new fibre-board containers and sealed for transport.

Table 2 illustrates a production flow chart.

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TABLE 2

Production Flow Chart:

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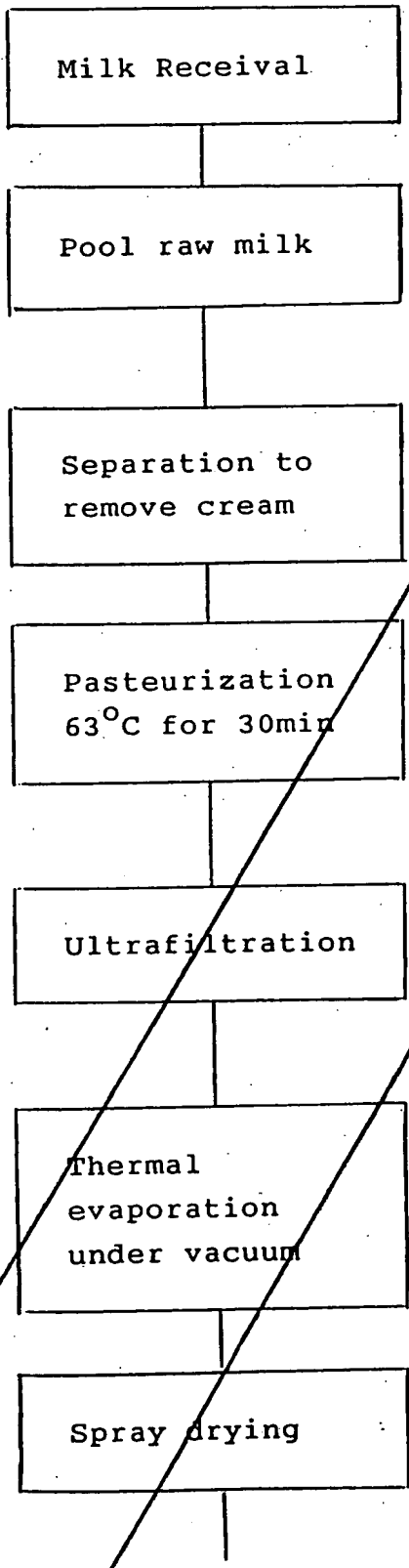



Raw milk is received, weighed and stored pending quality control and release.

Approved milk is pooled according to age and potency to produce a homogeneous batch of standard potency.

Cream (milk fat) is removed by separation in a standard dairy separator.

Milk is heated to 63°C and held for 30 minutes in a standard pasteurisation process, to eliminate pathogens and reduce total microbial load.

Product is concentrated by reduction of water, lactose and electrolyte levels through ultrafiltration membranes.

Product is further concentrated by low temperature evaporation under vacuum.

Product is spray dried in an aseptic spray drier.

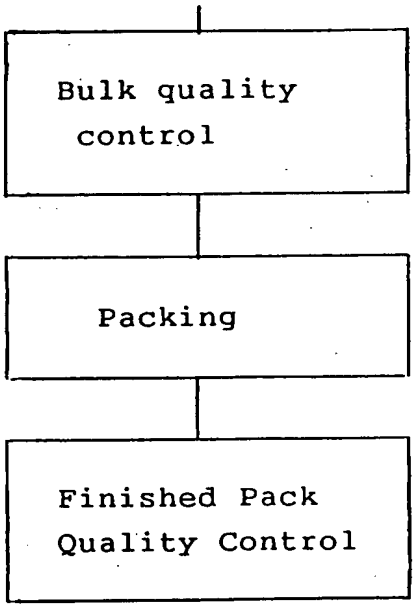
NOW AMENDED

TABLE 2

Production Flow Chart:

| | |
|---|---|
| Colostrum Receival | Raw colostrum is received, weighed and stored pending quality control and release. |
| Pool raw colostrum | Approved colostrum is pooled according to age and potency to produce a homogeneous batch of standard potency. |
| Separation to remove cream | Cream (milk fat) is removed by separation in a standard dairy separator. |
| Pasteurization $63^{\circ}C$ for 30min | Colostrum is heated to $63^{\circ}C$ and held for 30 minutes in a standard pasteurisation process, to eliminate pathogens and reduce total microbial load. |
| Ultrafiltration | Product is concentrated by reduction of water, lactose and electrolyte levels through ultrafiltration membranes. |
| Thermal evaporation under vacuum | Product is further concentrated by low temperature evaporation under vacuum. |
| Spray drying | Product is spray dried in an aseptic spray drier. |

AS AMENDED




Product is held in quarantine until approved for microbiological quality, moisture level and potency.

Approved bulk product packed into sachets. Packed product is returned for quality control.

Packed product is held in quarantine until approved for microbiological quality, moisture level, pack quality, potency and documentation review.

EXAMPLE 3

Table 3 lists the constituents of a sample of colostrum product which has been prepared by the process of Example 1.

TABLE 3

| | Colostrum Product Prepared by Process of Example 1 |
|---|---|
| Moisture % | 8.2 |
| Fat % | 2.4 |
| Solubility Index | 5.0 |
| Sc.Pts./Ext. Matter | D |
| Protein (TN x 6.38)% | 73.6 |
| Lactose % | 11.2 |
| Ash % @ 500°C | 5.9 |
| Salt % | 0.48 |
| Whey Protein Nitrogen mg/g | >7.0 |
| Dispersability% | 50 |
| Wettability (Secs) @ 25°C | 60+,60+,60+ |
| Aluminium mg/kg | 3.4 |
| Penicillin | <0.0025 |
| Other Inhibitory Substances (As Penicillin I.U./mL) (I.U./mL) | <0.0025 |

The above process reduces salt content by a factor of approximately eight times. First colostrum contains approximately 32 mmol/L of NaCl. If concentrated 20 fold as in the process described the salt content of the powder would be 640 mmol/kg, which is equivalent to 3.7% of the total weight. This concentration of salt could seriously affect the stainless steel surfaces of the spray drier.

The process described reduces the salt content from 3.7% to less than 0.5% of the final powder, significantly reducing the risk of corrosion, and negating the need for frequent wet cleansing procedures as described.

Finally, it is to be understood that various other modifications and/or alterations may be made without departing from the spirit of the invention,

which is defined in the following claims.

WHAT WE CLAIM IS:

1. A process for the preparation of a colostrum product which process includes

providing colostrum;

subjecting the colostrum to an ultra-filtration process; and

subjecting the filtered colostrum to a spray drying process, with proviso that the colostrum is not treated with acid to adjust pH to 5.0-6.0 and with rennin or pepsin to separate casein.

2. A process as claimed in claim 1 wherein a hollow fibre ultra-filtration apparatus is used to remove or substantially reduce the low molecular weight salt content of the colostrum.

3. A process as claimed in claim 1 or claim 2 wherein said ultra-filtration process removes substantially all molecules of molecular weight less than substantially 20,000.

4. A process as claimed in any preceding claim wherein the ultra-filtration process removes and reduces the lactose content of the colostrum.

5. A process as claimed in any preceding claim further including subjecting the colostrum to a pasteurisation process.

6. A process as claimed in claim 5 wherein the pasteurisation process takes place prior to the ultra-filtration process.

7. A process as claimed in any preceding claim wherein the process includes a step of separating the colostrum into a light phase and a heavy phase.

8. A process as claimed in claim 7 wherein said light phase is discarded.

9. A process as claimed in claim 7 or claim 8 wherein the separation step takes place prior to the pasteurisation process.

10. A process as claimed in any preceding claim wherein the ultra-filtered colostrum is subjected to an evaporation step to remove excess moisture from the colostrum.

11. A process substantially as hereinbefore described with reference to any one of the examples or drawing.

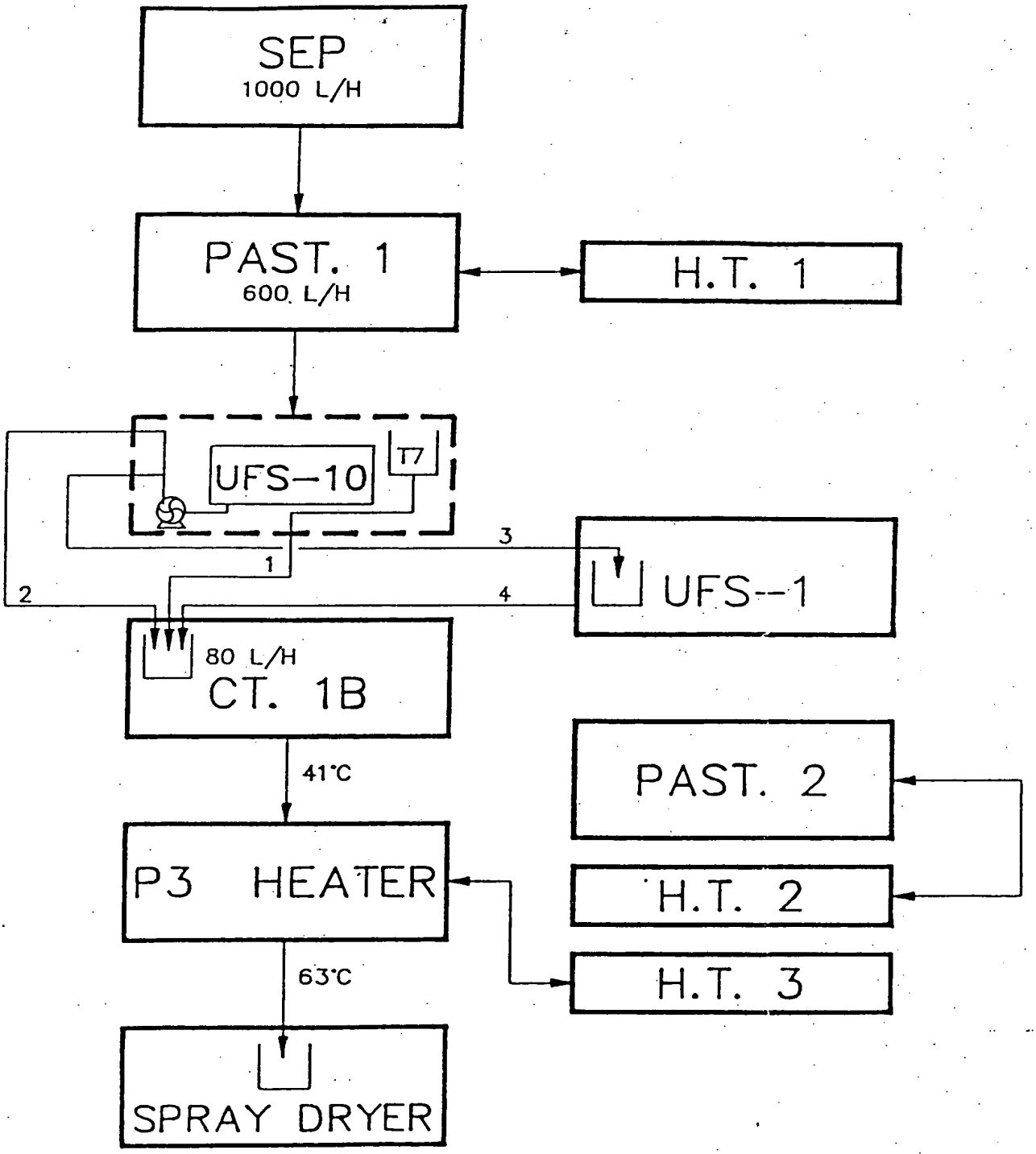
12. A colostrum product produced by the process of any preceding claim.

WEST-WALKER, McCABE

per: [signature]

ATTORNEYS FOR THE APPLICANT

FIGURE 1

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